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Mark A. Holland

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ELMORE PATENT LAW GROUP, PC
515 Groton Road
Unit 1R
Westford, MA 01886

EXAMINER

KINSEY WHITE, NICOLE ERIN

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Status of the Claims

Accordingly, claims 1, 2, 4, 5, 7-10, 23, 24, and 49-52 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 23, 24, and 49-52 remain are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to, *inter alia*, an isolated bacteriophage which is lytic for *Methylobacterium* species, Human blood bacterium (HBB), or both. Applicants have isolated and deposited bacteriophage that is lytic for *Methylobacterium* species and Human blood bacterium as ATTC# PTA-5075. However, applicants' claims encompass bacteriophage that are lytic for *Methylobacterium* species and Human blood bacterium and that are structurally and biologically different from ATTC# PTA-5075.

The written description rejection is made because the claims are interpreted as being drawn to a genus of bacteriophage which possesses the function of being lytic for *Methylobacterium* species or Human blood bacterium. The applicable standard for the

written description requirement can be found in MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Probe Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004). To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the specification is a single bacteriophage that was isolated and has the function of lysing PPFM. There is no disclosure of sufficient characteristics of the claimed genus to allow persons of ordinary skill in the art to recognize that applicants were in possess of the claimed genus.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. A definition by function alone is not sufficient because it is only an indication of what a thing does, rather than what it is. EliLily, 119 F.3 at 1568, 43 USPQ2d at 1406.

The court clearly states in Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for

purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented what is claimed. As discussed above, the skilled artisan cannot envision the distinguishing, identifying characteristics of the encompassed genus of bacteriophage. Given that the specification has only described the function of the bacteriophage, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

Response to Arguments

In the reply dated April 9, 2008, applicants argue that applicants were clearly in possession of the class of bacteriophage as evidenced by the specific bacteriophage described in the specification. Applicants also submitted a Declaration under 37 CFR §1.132 by Richard Carlton, M.D. Applicants' arguments and Declaration have both been fully considered, but are not found persuasive.

As outlined above, applicants have not provided sufficient identifying characteristics of the genus of bacteriophage encompassed by the claims. Applicants have only isolated (deposited) one phage (ATTC# PTA-5075) that is lytic for *Methylobacterium*.

Applicants' Declaration states that there is abundant evidence from a variety of authoritative sources that the phage isolated by Professor Holland represents something that is generalizable (repeatable). The Declaration further states that had Professor Holland wanted to find other phage strains, the collective experience of phage

researchers would predict that Professor Holland would have found a smorgasbord of different phage strains.

The fact that applicants isolated a phage using a repeatable or generalizable process is not at issue nor is what Professor Holland would have found had he searched for additional strains of phage that were lytic for *Methylobacterium*. What is at issue is whether or not applicants have provided adequate written description of the claimed genus. As outlined above, describing or depositing only one specific phage is not sufficient to show that applicants were in possession of the genus of phages that are lytic for *Methylobacterium*.

On page 5 of the Declaration, applicants argue that:

[o]nce Professor Holland had obtained that virulent anti-PPFM phage strain, and had demonstrated that it worked well in decreasing the rate (and vigor) of germination of seeds, he had no scientific need to search and isolate even more such phage strains, in addition to the variety he had already obtained. His quest was not that of a phage epidemiologist, who would want to find out how many strains of phages (against the target bacterial species) are present, or what they look like morphologically, or what their genetics are.

Applicants' statement supports the assertion that applicants were not in possession of the claimed genus because there was "no scientific need to search and isolate even more such phage strains" beyond the anti-PPFM strain ATTC# PTA-5075. Professor Holland was interested in finding one phage to suit his purposes (seed-curing). When he isolated that one phage, he looked no further. One phage is not sufficient to fully describe a genus of phages that all share the same function of lysing *Methylobacterium*. Describing many strains of phages against *Methylobacterium*, or describing what they

look like morphologically, or describing their genetic makeup would provide additional support that applicants were in possession of the claimed genus, however, the specification does not describe such characteristics. Therefore, because there is no disclosure of sufficient characteristics of the claimed genus, one of ordinary skill in the art would not recognize that applicants were in possession of the claimed genus.

In the reply dated September 10, 2008, applicants argue that the Office has allowed other claims to a genus based on the function and the same should be done for the instantly claimed bacteriophage.

Applicants' argument has been fully considered but not found persuasive. Each application before the Office is examined on its own merits. When examining one application, no consideration is given as to why other applications were allowed. Further, the patent claims presented by applicants in their argument are of a totally different subject matter.

As outlined above, the specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented what is claimed (i.e., a genus of bacteriophage lytic for *Methylobacterium* species). Applicants have only isolated and deposited one phage (ATTC# PTA-5075) that is lytic for *Methylobacterium*. The skilled artisan cannot envision the distinguishing, identifying characteristics of the encompassed genus of bacteriophage. Given that the specification has only described the function of the genus of bacteriophage, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

Allowable Subject Matter

Claims 2 and 7-10 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648